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PATTERSON & SHERIDAN, L.L.P.
3040 POST OAK BOULEVARD
SUITE 1500
HOUSTON, TX 77056

EXAMINER	
SASAN, ARADHANA	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,284	MAYER ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 17-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 17-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and claims filed on 06/12/09 are acknowledged.

2. No claims were amended.

3. Claims 1-12 and 17-29 are included in the prosecution.

MAINTAINED REJECTIONS:

The following is a list of maintained rejections:

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 17, 22, 24 and 26 **remain** rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. The term "less than about" is a relative term, which renders the claims indefinite. The term "less than about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Please see MPEP 2173.05(b).

Response to Arguments

4. Applicant's arguments, see Page 14, filed 06/12/09, with respect to the rejection of claims 17, 22, 24 and 26 under 35 USC § 112, second paragraph, as being indefinite

(with respect to the terms "less than about") have been fully considered but are not persuasive.

Applicant directs the Examiner to the present specification (Page 8, lines 24-27) which states an average diameter is measured as z average by quasielastic light scattering or photon correlation spectroscopy. Applicant argues that ordinary people [of] skill in the art would reasonably appreciate the scope of the invention as a standard for determining average size of the capsules is disclosed in the specification.

This is not persuasive because although the instant specification discloses the measurement of the average diameter, the limits of "less than about" are not disclosed. It is not defined if "less than about" includes 5nm, 2nm. In this respect, "less than about" is still unclear and indefinite. Therefore, the rejection of 03/05/09 is maintained.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-3, 5-11, 17-20, 22-24, 27, and 29 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Parikh et al. (US 2002/0106403 A1) in view of Caruso et al. (EP 1 116 516 A1).

The claimed invention is a solid dosage form for oral administration comprising a coherent matrix with a disintegration time of less than 2 minutes, wherein: the matrix comprises an active ingredient which is slightly soluble in a physiological fluid and which

is in the form of fast-release capsules selected from at least one of micro- and nanocapsules, the capsules comprising a core and a shell, the core comprising the slightly soluble active ingredient, the shell consists essentially of a material with high permeability for the slightly soluble active ingredient, the shell of the capsules comprising a complex of at least one polyelectrolyte and a counter ion to the polyelectrolyte, the shell is stable to allow diffusion and release of the active ingredient, while maintaining a stable aqueous suspension during release of the active ingredient, and the shell comprising a high permeability to release the slightly soluble active ingredient within 60 minutes.

Parikh discloses a solid dosage form for oral administration comprising a coherent matrix with a disintegration time of less than 30 seconds (Page 4, [0024]), wherein the matrix comprises an active ingredient which is slightly soluble in a physiological fluid (poorly soluble) (Page 2, [0010]). Parikh discloses mixing the active ingredient with matrix-forming, physiologically acceptable excipients to provide a mixture and forming the mixture into dose units (tablet) (Page 3, [0022]) and the active ingredient is in the form of fast-releasing microcapsules (phospholipid-coated microparticles) (Page 2, [0012] and Page 4, [0025]). Parikh discloses the microcapsules comprising a core (microparticle) and a shell (coating), wherein the core comprises the slightly soluble active ingredient. Since the microcapsule is considered to be rapid-releasing, the shell is also considered to have a high permeability. Parikh further discloses the microcapsules having an average size of less than 10μm (Pages 2-3, [0017]).

Parikh fails to expressly disclose the shell of the microcapsules comprising of at least one polyelectrolyte and a counter ion to the polyelectrolyte.

Caruso discloses using microparticles having shell comprising an amphiphilic (phospholipid) and alternating layers of polyelectrolytes of opposite charges, where the polymer layers are self-assembled by means of electrostatic layer-by-layer deposition (Page 2, [0009], Page 4, [0019]). Caruso further discloses controlling the permeability and porosity of the capsule by controlling the number of layers and by the selection of the polyelectrolytes used for the shell (Page 5, [0032], Page 6, [0036]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition with a matrix comprising fast releasing microcapsules, as suggested by Parikh, modify the composition of the shell of the microcapsule, as taught by Caruso, and produce the instant invention.

One of ordinary skill in the art would find it obvious to modify the matrix composition of Parikh by choosing from a finite number of predictable compositions for microparticles, such as the edible films with microcapsules as evidenced by Caruso, with a reasonable expectation of success of producing a functional film comprising microcapsules that provides rapid disintegration and dissolution of the active ingredient.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding the limitations of instant claims 1, 2, 6-9, 17, 18, 19, 22, 24, 27 and 29, Parikh teaches a solid dosage form for oral administration comprising a coherent matrix with a disintegration time of less than 30 seconds (Page 4, [0024]), wherein the matrix comprises an active ingredient which is slightly soluble in a physiological fluid (poorly soluble) (Page 2, [0010]).

With respect to claim 3, the modified Parikh discloses the release of active ingredient is virtually complete within 1 minute (Page 4, [0025]).

With respect to claim 5, the modified Parikh discloses the slightly soluble active ingredient is an antihypertensive or a sedative (Page 2, [0013]).

With respect to claim 10, the modified Parikh discloses the matrix is produced by compressing a material selected from at least one of powder and granules (Page 3, [0022]).

With respect to claim 11, the modified Parikh discloses the matrix is produced by freeze-drying a substance selected from at least one of a fluid and a highly viscous composition (Page 2, [0011]).

With respect to claim 20, the modified Parikh discloses mixing the mixture with a liquid carrier (aqueous medium) to provide a solution, wherein forming the mixture into dose units includes dividing and freeze-drying the solution (Page 3, [0018]-[0020]).

With respect to claim 23, the modified Parikh discloses the active ingredient is a therapeutic (Pages 2-3, [0017]).

Response to Arguments

7. Applicant's arguments, see Page 7, filed 06/12/09, with respect to the rejection of claims 1-3, 5-11, 17-20, 22-24, 27, and 29 under 35 U.S.C. 103(a) as being unpatentable over Parikh et al. (US 2002/0106403 A1) in view of Caruso et al. (EP 1 116 516 A1) have been fully considered but are not persuasive.

Applicant argues that Parikh does not teach or suggest capsules having a core and a shell structure.

This is not persuasive because Parikh teaches microparticles and phospholipid coated drug particles (Page 2, [0012] and Page 4, [0025]). The core comprises the drug particle and the shell comprises the phospholipid. The structure is taught by Parikh.

Applicants argue that Parikh does not teach, suggest, or otherwise render obvious "the shell is stable to allow diffusion and release of the active ingredient, while maintaining a stable aqueous suspension during release of the active ingredient, the shell comprising a high permeability to release the slightly soluble active ingredient within 60 minutes," as recited in amended claim 1.

This is not persuasive because Parikh teaches rapid disintegration times (less than 2 minutes) (Page 4, [0024]). A rapid dissolution rate of the active ingredient from the microparticles (5-60 sec) is also disclosed (Page 4, [0025]). The shell of the microparticle implicitly allows diffusion and release of the active ingredient because of the rapid disintegration and rapid dissolution times. Parikh also teaches that the rate of dissolution and release can be intermediate (75% disintegration in 15 minutes), thereby implying that the shell of the microparticle allows the diffusion and release of the active

ingredient such that 75% of the microparticles disintegrate in 15 minutes, i.e., a stable aqueous suspension during release of the active ingredient is implicit.

Applicant argues that Parikh's surface modifier is adsorbed on to the surface of micronized particles and is dissolved together with the microparticles, which implies a non-stable capsule shell.

This is not persuasive because the surface modifiers disclosed by Parikh include phospholipids, gelatin, and carboxymethylcellulose (Page 2, [0015]). Although Parikh labels these materials as surface modifiers because of their surfactant properties, the fact remains that these form the coating on the core comprising the active material to produce microparticles that have a particle size between 0.05μm to 10 μm (Pages 2-3, [0015] – [0017]). Moreover, Applicants have also disclosed these same materials, particularly a combination of lipids and polymers (including carboxymethylcelluloses) that are used for preparing the capsule shell (Instant Specification, Page 9, lines 9-39).

Applicants argue that the term "dissolve" or "disintegrate" as described in Parikh's specification clearly suggests a non-stable capsule shell and that the explanations for the term "dissolve" or "disintegrate" matches Parikh's description that the surface modifier is dissolved together with the microparticles. Applicants point to Parikh's arguments during the prosecution history of that particular application and argue that it becomes evident that the adsorbed surface modifier, i.e., the alleged shell, is not in a stable status that allows the drug component to diffuse through during release of the drug component, but rather rapidly dissolved together with the drug component in an aqueous environment as described in Parikh's disclosure. Applicants argue that the

drug in Parikh's particles can be released only by disintegration of the particle, not by diffusion, since the phospholipid coating represents a stable barrier and that the resulting drug release rate will depend on the composition of the particles as a whole.

This is not persuasive because, as noted above, Parikh discloses that materials such as phospholipids, gelatin, and carboxymethylcellulose (Page 2, [0015]) form the coating on the core comprising the active material to produce microparticles that have a particle size between 0.05μm to 10 μm (Pages 2-3, [0015] – [0017]) and that the rate of dissolution and release can be intermediate (75% disintegration in 15 minutes), thereby implying that the shell of the microparticle allows the diffusion and release of the active ingredient such that 75% of the microparticles disintegrate in 15 minutes, i.e., a stable aqueous suspension during release of the active ingredient is implicit. Since the components of the claimed composition (core comprising an active ingredient and capsule shell material) are taught by Parikh along with the particle size and the rapid/intermediate release, one of ordinary skill in the art would find it obvious that the microparticle will be stable for the duration of the intermediate release or dissolution.

Applicants argue that a skilled artisan would not consider an additional polyelectrolyte coating of Parikh's particles according to Caruso as such polyelectrolyte coating atop the phospholipid coating would stabilize it even further. Applicant argues that the resulting inhibition of drug release would lead away from the declared goal of the subject application for fast release drug formulation and therefore, the approach to combine Caruso with Parikh would lead a skilled artisan away from the present

invention. Applicants submit that a notional combination of Parikh and Caruso is an impermissible hindsight consideration.

This is not persuasive because it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the microparticle capsule shell of Parikh by choosing from a finite number of predictable capsule shell materials for microcapsule or microparticle formulations (such as phospholipids and polyelectrolytes with opposing charges), as evidenced by Caruso, with a reasonable expectation of success of producing a functional microparticle that provides rapid disintegration and dissolution of the active ingredient. The simple substitution of one known element for another to obtain predictable results is obvious. Please see MPEP 2141.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Therefore the rejection of 03/05/09 is maintained.

Claim Rejections - 35 USC § 103

8. Claims 4, 25-26, and 28 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Parikh et al. (US 2002/0106403 A1) in view of Caruso et al. (EP 1 116 516 A1) and further in view of Allen et al. (US 6,187,337 B1).

The teachings of Parikh and Caruso are stated above.

Although Parikh discloses gelatin and mannitol as matrix forming agents (Page 3, [0018]), the reference does not expressly teach gelatin and mannitol (in the matrix) in a ratio of 1:1 to 1:3.

Allen teaches rapidly dissolving dosage forms comprising a particulate matrix (Abstract). In examples 32 and 33, the calculated ratio of mannitol: gelatin is 2.9:1 (example 32: 16.0g of mannitol/5.5g total gelatin) and 2.13:1 (example 33: 16.0g mannitol/7.5g total gelatin) (Col. 27, line 30 to Col. 28, line 14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition with a matrix comprising fast releasing microcapsules, as suggested by Parikh, modify the composition of the shell of the microcapsule, as taught by Caruso, use the ratio of gelatin and mannitol in a rapidly dissolving dosage form, as suggested by Allen, and produce the instant invention.

One of ordinary skill in the art would do this because Allen teaches a rapidly dissolving dosage form and gelatin and mannitol are known components of matrices of rapidly dissolving dosage forms (as evidenced by Parikh and Allen). Where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding instant claim 4, the limitation of the matrix further comprising gelatin and mannitol in a ratio of 1:1 to 1:3 would have been obvious over the gelatin and mannitol disclosed by Parikh as matrix forming agents (Page 3, [0018]) in view of the calculated ratio of mannitol: gelatin is 2.9:1 (example 32: 16.0g of mannitol/5.5g total gelatin) and 2.13:1 (example 33: 16.0g mannitol/7.5g total gelatin) respectively (Col. 27, line 30 to Col. 28, line 14), as taught by Allen. One of ordinary skill in the art would find it obvious to try different levels and ratios of the matrix components during the process of routine experimentation depending on the desired disintegration and dissolution/release rate. The recited ratio of gelatin and mannitol would have been an obvious variant unless there is evidence of criticality or unexpected results.

Regarding instant claim 25, the limitation of the slightly soluble active ingredient would have been obvious over the antihypertensive or sedative taught by Parikh (Page 2, [0013]).

Regarding instant claim 26, the limitation of the average size of the capsule that is less than about 10 μm would have been obvious over the microcapsules having an average size of less than 10μm, as taught by Parikh (Pages 2-3, [0017]).

Regarding instant claim 28, the limitation of the shell of the capsule that comprises a material selected from at least one of a lipid layer and a lipid bilayer would have been obvious over the microcapsules comprising a lipid layer (phospholipid), as taught by Parikh (Page 4, [0025]).

Response to Arguments

9. Applicant's arguments, see Page 13, filed 06/12/09, with respect to the rejection of claims 4, 25-26, and 28 under 35 U.S.C. 103(a) as being unpatentable over Parikh et al. (US 2002/0106403 A1) in view of Caruso et al. (EP 1 116 516 A1) and further in view of Allen et al. (US 6,187,337 B1) have been fully considered but are not persuasive.

Applicant argues that although Allen mentions the ratio of mannitol and gelatin, Allen does not teach or suggest the active material to be encompassed by a material with high permeability. Applicant argues that Allen does not teach, suggest, or otherwise render obvious "fast-releasing capsules having a high permeability for the slightly soluble active ingredient," and "the shell is stable to allow diffusion and release of the active ingredient, while maintaining a stable aqueous suspension during release of the active ingredient, the shell comprising a high permeability to release the slightly soluble active ingredient within 60 minutes," as recited in claim 1.

This is not persuasive because rapidly dissolving dosage forms with matrices of gelatin and mannitol are known in the art (as evidenced by Parikh and Allen). One of ordinary skill in the art would combine Allen with Parikh because both references teach rapidly dissolving dosage forms. Combining prior art elements according to known methods to yield predictable results is obvious. Please see MPEP 2141.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Therefore, the rejection of 03/05/09 is maintained.

Claim Rejections - 35 USC § 103

10. Claims 12 and 21 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Parikh et al. (US 2002/0106403 A1) in view of Caruso et al. (EP 1 116 516 A1) and further in view of Virgalitto et al. (US 2005/0089548 A1).

The teachings of Parikh and Caruso are stated above.

Parikh and Caruso do not expressly teach that the matrix is produced by solidifying a composition which has been spread out into a film.

Virgalitto discloses microcapsules containing active ingredients, such as pharmaceutical active ingredients, in an edible film (matrix) (Page 1, [0012], and Page 4, [0043]). Virgalitto further discloses the matrix is produced by solidifying a composition which has been spread out into a film (Page 5, [0074]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of making the matrix in order to create an alternative oral dosage form for patients that are unable or have a difficult time swallowing conventional oral dosage forms, as taught by Virgalitto (Page 1, [0002]).

Regarding claims 12 and 21, the modified Parikh addresses all the limitations of claim 18, however fails to expressly disclose mixing the mixture with a liquid carrier (inherent to aqueous solution) to provide a solution, wherein forming the mixture into dose units includes spreading the solution into a film and drying the film. Virgalitto

discloses the edible film is formed by mixing the mixture (microcapsules and excipients) with a liquid carrier to provide a solution, spreading the solution into a film and drying the film (Page 5, [0074], Page 6, [0076]).

Response to Arguments

11. Applicant's arguments, see Page 13, filed 06/12/09, with respect to the rejection of claims 12 and 21 under 35 U.S.C. 103(a) as being unpatentable over Parikh et al. (US 2002/0106403 A1) in view of Caruso et al. (EP 1 116 516 A1) and further in view of Virgalitto et al. (US 2005/0089548 A1) have been fully considered but are not persuasive.

Applicant argues that Virgalitto teaches a sustained release mechanism using microcapsules (edible film) contained with an active agent and that although Virgalitto mentions the use of microcapsules containing active agents, Virgalitto's film is rapidly dissolved, break-down and disintegrated upon contact with moisture to release the active agent.

This is not persuasive because microcapsules containing active ingredients, such as pharmaceutical active ingredients, in an edible film (matrix) are known in the art, as evidenced by Virgalitto (Page 1, [0012], and Page 4, [0043]), which is used as a secondary reference. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the matrix composition of Parikh by choosing from a finite number of predictable compositions for microparticles, such as the edible films with microcapsules as evidenced by Caruso, with a reasonable expectation of

success of producing a functional film comprising microcapsules that provides rapid disintegration and dissolution of the active ingredient.

Therefore, the rejection of 03/05/09 is maintained.

Conclusion

12. No claims are allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, TC 1600